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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,400	12/27/2000	Thomas Specht	SCH-1779	7219

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/03/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/673,400

Applicant(s)

SPECHT ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 27-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-38 and new claims 39 and 40 are pending in the present application. Claims 23-26 are currently under consideration. This Office action is in response to Paper No. 15 filed 28 February 2003.

Election/Restrictions

Newly submitted claims 39 and 40 and newly amended claims 27-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The present claims are drawn to an isolated polypeptide elected for examination by Applicant in Paper No. 12, filed 1 August 2002. Claims 39 and 40 are drawn to a method for determining whether a compound is active against hystero myoma. Claims 27-31 were filed as use claims which are inappropriate subject matter under 35 U.S.C. 101. Applicant has amended these claims to now recite an isolated nucleotide, which is a different product, a method for preparing a pharmaceutical composition, a method for finding an active ingredient, and a method for treatment. Each of these methods and products, which are now recited in claims 27-31, require a new search for which a serious search burden to the examiner exists. These claims are drawn to separate and distinct inventions. Had these claims been originally filed they would have been subject to the restriction requirement, mailed on 1 July 2002.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, new claims 27-31 and amended claims 39 and 40 as well as originally filed claims 1-22 and 32-38 are withdrawn from consideration as being directed to a

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non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 23-31 and SEQ ID NO:38 are currently under consideration.

Response to Amendment

Claim 25 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Upon further consideration and in view of the new grounds of rejection below, the rejection of claims 23, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, has been withdrawn.

The rejection of claims 23-26 under 35 U.S.C. 102(b) as being anticipated by Accession Number Q00833. (Mol. Gen Genet. Vol.249 1995) has been withdrawn in view of Applicant's amendment wherein the claims are no longer drawn to polypeptide fragments or partial sequences.

The rejections of claims 27-31 under 35 U.S.C. 112, second paragraph and 35 U.S.C. 101 have been withdrawn in view of Applicant's amendment.

Response to Arguments and New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Applicant’s claims are drawn to sequences having 80% homology with SEQ ID NO:38 that can bind to the polypeptide sequence of SEQ ID NO:38, which includes fragments and partial sequences. These are genus claims that encompass a wide array of molecules. The specification does not disclose any of the variants or modifications, nor does it provide any teachings as to how the structures of these sequences relate to their function. The specification does not describe the complete structure of the sequence in such a way that one of skill in the art would reasonably conclude that Applicant was in possession of the invention. Since these claims

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are drawn to a polypeptide, it is well-known in the art that a single residue change or deletion could eliminate or change the function of the polypeptide. To overcome this problem Applicant should provide information relating the structure of the sequences such as motifs, domains or consensus sequence that relate to a specific function to support claims to such a broad genus. In other words, Applicant has failed to describe the invention in terms of partial structure and relevant identifying characteristics. Absent such teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed polypeptides in such full, clear, concise and exact terms such that Applicant had possession of these molecules at the time of filing of the present application.

Applicant has argues with regard to claim 25, and appears to be applicable to the newly rejected claims, that SEQ ID NO:38 indeed has a function as a human mRNA putatively prenylated protein and further that expression data indicates that SEQ ID NO:38 is expressed in tumorous ovarian and breast tissue. First, it is not clear to the examiner how a putative prenylated protein is a function at all. The word “putative” indicates to the examiner that Applicant is not sure that what the activity of the protein is and is merely presuming its activity. Also, prenylation is a mechanism by which proteins are anchored to the inner surface of mammalian cell membranes. See Lehninger, page 813. It appears that applicant is saying that the protein might be attached to the surface of a cell membrane by a farnesylation reaction. If this is true, then the function of the protein is still unknown as is the relationship between the protein's structure and function. Second, the expression of the sequence in tumorous ovarian and breast tissue does not establish a function of the claimed protein.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23-26 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The present claims are drawn to a polypeptides and homologous sequences of SEQ ID NO:38. Although the specification prophetically asserts using the claimed proteins in various protocols and recombinant technology including searching for tumor related candidate genes and chromosomal mapping. No evidence or guidance is provided that would suggest to a skilled artisan that there is any utility in using the protein of SEQ ID NO:38. since Applicant has not adequately describe any specific activity for the alleged protein. Thereby, it is doubtful whether the nucleotide sequences or their encoded proteins can be used in any of Applicant's asserted utilities.

Additionally, the specification's lack of a specific and substantial asserted utility or a well established utility is further supported by the specification which notes that a search of the proteins encoded by the claimed sequences merely revealed expression of SEQ ID NO:38 in tumorous breast and ovarian tissue. See Paper 15, page 4. First, this assertion leaves open the possibility that breast and ovarian tissue other than the tumor as well as other human tissues express the protein. Second, even if the protein is found in breast and ovarian tumor tissue alone, this does not translate to an activity for which there is a use. It is established in the case law, that a patent is not a "hunting license" it is "not a reward for the search, but compensation for a successful conclusion." See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966). The

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skilled artisan would need to prepare and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form such that further experimentation on the protein itself would be required before it could be used. As discussed above, neither the art nor the specification as filed provides a specific and substantial asserted utility or a well established utility for the claimed polypeptide sequence; thereby casting doubt on the utility of the claimed invention.

Claims 23-26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
May 31, 2003


JAMES KETTER
PRIMARY EXAMINER